

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)
PHARMACY, INC., PRODUCTS LIABILITY)
LITIGATION)
) MDL No.: 2419
) Master Docket No.: 1:13-md-2419-FDS
-----)
THIS DOCUMENT RELATES TO:)
)
All actions.)

PROPOSED ESI PROTOCOL

This protocol shall apply to all discovery of electronically stored information. It may be supplemented or amended by subsequent agreement of the Parties in light of further developments or by the Court.

I. DEFINITIONS

A. "Electronically stored information" or "ESI," as used herein, has the same meaning as contemplated by the Federal Rules of Civil Procedure. *See, e.g.*, F.R.C.P. 34.

B. "Incremental Costs" are the reasonable costs of transferring data to Production Media (e.g., CD-ROM, DVD, external hard drive, etc.) and the reasonable cost of the Production Media itself. For costs charged by a vendor, the Responding Party will request and provide a separate invoice detailing the Incremental Costs being taxed to the receiving Party.

C. "Native format" means and refers to the format of ESI in which it was originally created or normally kept by the Responding Party in the usual course of its business and in its regularly conducted activities.

D. "Metadata" means and refers to information about information or data about data, and includes without limitation (i) information embedded in or associated with a native file that

is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage, and/or validity of the electronic file and/or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted, or otherwise manipulated by a user of such system.

E. “Static Image” means or refers to a representation of ESI produced by converting a native file into a standard image format capable of being viewed and printed on standard computer systems.

F. “Documents” has the meaning contemplated in the Federal Rules of Civil Procedure. *See, e.g.*, F.R.C.P. 34.

G. “Media” means an object or device, including but not limited to a disc, tape, drive, computer or other device on which data is or can be stored.

H. “Parties” means or refers to the named parties in the above-captioned matter, as well as any later added parties.

I. “Responding Party” means or refers to the party responsible for responding to discovery requests.

J. “Requesting Party” means the party that propounded discovery requests.

II. SCOPE

A. General. The procedures and protocols set forth in this Agreement shall govern the production of ESI in this matter, unless the Parties agree in writing to change them or they are changed by the Court. Without limiting the generality of the foregoing, the Parties will confer in good faith regarding proposed changes to the Agreement in view of specific discovery requests made during the course of this litigation and/or in view of issues arising after a Party commences collection of ESI and other documents and information. In the absence of an

agreement between the Parties to change this Agreement, any Party may apply to the Court for relief. Nothing in this Agreement constitutes the waiver or estoppel of a Party's right to seek amendments to this Agreement for good cause, including without limitation changed, unforeseen or unknown circumstances at the time the Parties entered this Agreement. Nor does anything in this Agreement waive the right of any Party to object to the production of certain documents or ESI, including on the basis of relevance, undue burden, and/or inaccessibility.

B. Disputes. The Parties shall meet and confer in good faith on any issues regarding ESI that arise under this Agreement or otherwise, including any issues relating to custodians and data sources. In the event the Parties cannot reach an agreement on a disputed matter, the Parties shall submit the matter to the Court. For any disputes regarding the most effective way to retrieve or obtain requested ESI, the Parties or their representatives shall be knowledgeable about the matters at issue when they meet and confer. Both sides should be prepared to discuss specifically the relevance of the information sought, other sources of similar information, the burden of producing the information, and the parameters of the search.

III. SEARCH TERMS AND PROTOCOL FOR ELECTRONIC DOCUMENTS

The Parties agree to use search terms as one methodology for narrowing the universe of ESI that is potentially responsive to discovery requests served by the Parties in the above-captioned matter. To the extent necessary, each Party reserves the right to use additional document review technologies, such as predictive coding software, to further refine the universe of ESI that is potentially responsive discovery requests. To the extent that the universe of ESI that is potentially responsive to discovery requests is narrowed by additional document review technologies, other than the agreed upon search protocols, such technologies shall be disclosed to the other Party and any objections to the use of additional technologies are reserved.

Contemporaneously with serving responses and objections (or within fourteen days after this Protocol is entered by the Court, whichever is later), the Responding Party shall identify:

1. Any limitations on ESI in accordance with Federal Rule of Civil Procedure 26(b)(2)(B);
2. The sources of data that the Responding Party intends to search for responsive ESI; and
3. The custodians whose documents the Responding Party intends to search for responsive ESI and shall provide a list of custodians that the Responding Party intends not to search. If, based on the size and scope of a Responding Party's operations, it is not feasible to list every custodian not searched, the Responding Party shall provide a list of categories (i.e. job titles, geographic location, etc.) of custodians the Responding Party intends not to search. The Responding Party's list of proposed custodians will include each such custodian's job title. Each Party shall retain the right, upon reviewing documents actually produced in the litigation and conducting other investigation and discovery, to request that files from additional custodians be searched later in the litigation. The Parties agree to meet and confer in good faith concerning any such requests.

With respect to search terms, within fourteen days of serving their objections and responses to another Party's requests for production (or within fourteen days after this Protocol is entered by the Court, whichever is later), the Parties shall meet and confer and:

1. Propose keyword search terms (including semantic synonyms, code words, acronyms, abbreviations, non-language alphanumeric associational references to relevant ESI, etc.) to be used when searching for ESI.

2. Propose exclusion criteria (including, but not limited to date restrictions) related to ESI searches.

Within thirty days of serving their objections and responses to another Party's requests for production (or within thirty days after this Protocol is entered by the Court, whichever is later), the Parties shall circulate lists of agreed and disputed custodians and sources, agreed and disputed search terms, and agreed and disputed exclusion criteria. Notwithstanding the foregoing, in the event that a Responding Party subsequently determines in good faith that an agreed term should not have been included or that the term has resulted in or is likely to result in undue burden, the Parties shall cooperate in good faith to resolve the matter. Any Party proposing such modifications to the agreed search terms must demonstrate good cause for such modification. In the absence of a mutually acceptable agreement to modify the agreed searched terms, the Parties may submit the dispute to the Court.

No later than seven days after the date on which the Parties reach agreement on custodians, data sources, and search terms, each Party shall begin collecting documents, ESI, and information for review and potential production as required by the Federal Rules of Civil Procedure (the "Collected Documents"). In the event that the Parties are unable to reach agreement on custodians, data sources, and search terms and the dispute is submitted to the Court, each Party may delay collection efforts over the disputed custodians, data sources, and/or search terms until after the dispute is resolved by the Court, but Collection efforts over agreed custodians, data sources, and search terms shall proceed.

To the extent reasonably possible, the Responding Party shall apply all agreed search terms to the Collected Documents. All queries shall be run in a non-case sensitive manner, unless otherwise agreed by the Parties. Queries of family groups (e.g., email and attachments)

will be run against all members of a family group, and if any is responsive to a search term, the entire family group shall be treated as responsive to that search term.

Subject to Defendants' responses and objections, documents responsive to search terms will be reviewed for responsiveness to Plaintiffs' document requests and selected for production in accordance with the Federal Rules of Civil Procedure. Production of responsive documents will be done on a rolling basis, and will not await the identification of all Collected Documents or all custodians.

The Collected Documents are likely to include non-searchable documents such as .wav files, .mpeg files and non-OCR's .pdf files (the "Non-Searchable Collection"). These documents will be treated as responsive and reviewed to the extent they are associated with a document that is otherwise responsive to a word search and document request. The Parties agree to meet and confer on the remaining Non-Searchable Collection and shall cooperate in good faith to determine the basis for review, if any, of the Non-Searchable Collection.

Each Responding Party may, at its election, further review documents for privilege prior to production or elect to forgo any privilege review prior to production to the receiving Party. In either event, in order to encourage expeditious discovery and minimize the costs of review, and pursuant to Federal Rule of Evidence 502(d), if the Responding Party discloses information in connection with the pending litigation that the Responding Party thereafter claims to be privileged or protected by the attorney-client privilege or work product protection ("Protected Information"), the disclosure of that Protected Information will not constitute or be deemed a waiver or forfeiture—in this or any other action—of any claim of privilege or work product protection that the Responding Party would otherwise be entitled to assert with respect to the Protected Information and its subject matter. The provisions of Fed. R. Evid. 502(b) are

inapplicable to the production of documents or information under this Order. The following procedure and stipulations shall apply:

1. Upon notice from the Responding Party that Protected Information has been disclosed, the Receiving Party shall immediately collect all copies of such Protected Information and return them to the Responding Party, and the parties will work in good faith to remove the Protected Information from any online document repositories where the Protected Information is located;
2. The Responding Party shall place the Protected Information on a privilege log; and
3. Any challenge to a claim of privilege shall proceed in accordance with the Federal Rules of Civil Procedure.

The Responding Party may also apply disputed search terms to a reasonable sample of documents from an agreed data source; provided, however, that the Responding Party reserves the discretion not to run searches and provide data for those terms which it believes, in good faith, are obviously and unreasonably overbroad (the “Refused Terms”). Nothing herein shall preclude an opposing Party from challenging another Party’s assessment of reasonableness. The Parties agree to meet and confer regarding any disputes that arise concerning the reasonableness of the sampling, including disputes concerning the methodology used to determine the sample.

On a rolling basis thereafter, each Party shall disclose, for each source of sampled documents, the number of aggregate and unique “hits” for each of the disputed search terms. The Parties shall, within one (1) week of such disclosures, meet and confer to discuss the utility of adding any, or all, of the disputed search terms. The Parties shall continue to meet and confer in good faith regarding any search process issues that arise throughout this process, including

any appropriate sampling of the documents with disputed search term “hits” to determine the utility of particular disputed search terms and the need to revise any of the procedures herein in light of the results of collection efforts.

If, at the end of the process described above, disputed search terms remain, the Parties will submit those terms to the Magistrate Judge in the form of a joint discovery letter with a discussion of the relevance and/or burden associated with each such term.

Once the files of a custodian are searched for all agreed terms (including any formerly disputed terms which, by agreement of the Parties or order of the Court, are encompassed therein), the Responding Party shall not be under any obligation, absent a Court order, to re-search that custodian’s files for additional search terms. Any Party proposing such additional search terms will have to demonstrate good cause for re-searching a custodian’s files.

The Parties will continue to meet and confer regarding any search process issues as necessary and appropriate throughout this process.

This ESI protocol does not address or resolve any objection to the scope of the Parties’ respective discovery requests, and it does not prevent any Party from undertaking additional searches of its own ESI for its own purposes at any time.

IV. FORMAT OF PRODUCTION

A. Document Image Format. Unless otherwise agreed to in writing by a Requesting Party, the Responding Party shall have the option of (a) producing documents electronically in native file format, or (b) electronically as a single-page Group IV “TIFF” image that reflects how the source document would have appeared if printed out to a printer attached to a computer viewing the file, along with the associated files and fields of metadata set forth below. A Party electing to produce documents in TIFF format pursuant to V.A.(b) shall bear the costs of producing the TIFF files.

1. If ESI has hidden text (e.g., track changes, hidden columns, comments, notes, markups, etc.) associated with it, the Parties shall produce the ESI in a form showing such hidden text to the extent reasonably practicable. When processing ESI for review and for production, to the extent reasonably practicable, the Responding Party will instruct its vendor to force off Auto Date and force on hidden columns or rows, hidden worksheets, speaker notes, track changes, and comments. If producing hidden text is not reasonably practicable, the parties shall meet and confer regarding possible alternatives.

2. Accompanying a TIFF production shall be a multipage text (.TXT) file containing searchable text from the native file, including, with regard to email, the email header text, and the metadata as discussed later in this document.

3. Load files of the Static Images shall be created and produced together with their associated Static Images to facilitate the use of the produced images by a document management or litigation support database system.

4. The Parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

B. Native File Format. Spreadsheets (e.g., Excel, Lotus), video/audio files (e.g., .wav, .mp3, .tiff, .wmv), and such other document types upon which the Parties may agree, will be produced in native format, except where such files are redacted in accordance with applicable law or Court order. If production in native format is necessary to decipher the meaning, context, or content of a document produced in the document image format agreed to pursuant to paragraph V.A., the Responding Party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of the

document in native format. All documents produced solely in native format should (i) have an assigned document level Bates number, (ii) be renamed according to the assigned Bates number, and (iii) have a “native path” populated along with the metadata load file pursuant to the guidelines outlined in paragraph V.J. Where a party produces a portion of a family of documents as TIFF images and a portion of the same family as native documents (such as a TIFF image of an e-mail and a native copy of the Excel spreadsheet that was attached to the e-mail), the TIFF images shall also be accompanied by a TIFF placeholder with the Bates number endorsed (“burned”) onto the image, as well as any confidentiality designation associated with that document. The Parties agree that compliance with these provisions shall not constitute spoliation.

C. Production of Hard Copy Documents. If a Responding Party has or intends to convert any hard-copy documents or records to Static Images, the Responding Party shall provide the Static Image files and corresponding load files to the Requesting Party pursuant to Section V.A. and the protocols set forth herein, or as otherwise agreed to by the Parties. Unless otherwise agreed to by the Parties, the Requesting Party shall pay the reasonable Incremental Costs, if any, of creating its copy of the Static Images and corresponding load files.

D. Document Unitization. For files produced as TIFF images, each page of a document shall be electronically saved as an image file. If a document consists of more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as it existed in the original when creating the image files. The Responding Party shall produce a unitization file (“load file”) for all produced documents in accordance with paragraph V.L.

E. Duplicates. To the extent that exact duplicate documents (based on MD5 or

SHA-1 hash values) reside within a Party's ESI data set, each Party may produce only a single copy of a responsive document or record ("Single Production Copy"), but the Parties are not required to do so. Exact duplicate shall mean bit-for-bit identicity of the document content. For exact duplicate documents where a Party elects to produce a Single Production Copy, the Responding Party will produce the metadata described in section V.J. herein for the Single Production Copy, as well as any such metadata that differs for the duplicate document(s). In such case, the Responding Party shall populate a field of data that identifies each custodian who had a copy of the produced document in addition to a separate field of data identifying the custodian whose document is produced. The Parties shall provide periodic updates to their load files if the Dup_Custodian field must be updated to account for newly processed data. No Party shall identify and eliminate duplicates by manual review or some method other than by use of the technical comparison using MD5 or SHA-1 hash values outlined above.

F. Color. At the Responding Party's option, hard copy documents and documents reduced to TIFF may be produced in black and white in the first instance. Notwithstanding the foregoing, the Responding Party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of a color image of the document (and, in the case of a hard copy document, a color hard copy) where the Requesting Party determines the color is reasonably necessary to decipher the meaning, context, or content of the document.

G. Bates Numbering and Other Unique Identifiers. For files produced in the document image format agreed to pursuant to paragraph V.A., each page of a produced document, at the sole option and non-reimbursable and non-taxable cost of the Responding Party unless otherwise agreed to in writing by a Requesting Party, shall have a legible, unique page

identifier (“Bates Number”) electronically “burned” onto the image in such a manner that information from the source document is not obliterated, concealed, or interfered with. There shall be no other legend or stamp placed on the document image unless a document qualifies for confidential treatment pursuant to the terms of a protective order entered by this Court in this litigation, or has been redacted in accordance with applicable law or Court order. In the case of confidential information or highly confidential information, as defined in a protective order, or materials redacted in accordance with applicable law or Court order, a designation may be “burned” onto the document’s image at a location that does not obliterate or obscure any information from the source document. A Party may uniformly “burn” the Bates Number on the same general area for an entire production (*e.g.*, lower right corner of every page) without violating the terms or conditions of this order. If the uniform placement of a Bates Number results in information being obscured, the parties will work together in good faith to obtain a copy of the document with the Bates Number relocated. Any Party producing ESI in a native format shall produce the document in the format agreed to pursuant to paragraph V.B.

H. Production Media. Documents shall be produced on CD-ROM, DVD, external hard drive (with standard PC compatible interface), or any other readily accessible computer or electronic media (the “Production Media”).

I. Electronic Text Files. Where the documents collected include those maintained in the ordinary course of business with searchable text, text files shall be produced reflecting the full text that has been electronically extracted from the documents (“Extracted Text”), including any hidden text. Where documents are no longer searchable because they have been converted to Static Images by the Responding Party after they were collected, the Responding Party shall provide OCR text files at its own expense. Where the documents collected do not contain

searchable text as they are maintained in the ordinary course of business (such as a non-searchable pdf attached to a responsive e-mail), the Requesting Party shall pay the reasonable Incremental Costs, if any, associated with obtaining its own copy of the OCR text files generated by the Responding Party, if any. With respect to emails, the Extracted Text shall include email header information, including to, from, cc, bcc, subject, date, and the names of attachment files. The Extracted Text shall be labeled and produced on Production Media in accordance with the provisions of paragraph V.H. above, "Production Media." The text files shall be produced in multi-page text file format and will be named in such a way that they can be associated with their corresponding Static Images in databases utilized by commercially available document management or litigation support software.

J. Metadata. The Parties agree to produce the following metadata fields (to the extent available) to accompany each produced ESI file.

- BegDoc (beginning Bates number of the first page of a document)
- EndDoc (ending Bates number of the last page of the document)
- BegAttach (Bates number associated with the first page of a parent document)
- EndAttach (Bates number associated with the last page of the last attachment to a parent document)
- Attach Count (number of attachments to an email or e-doc)
- DocTitle (e-docs only)
- ThreadID (emails only)
- Thread_in_Reply_to (emails only)
- Thread_references (emails only)
- File/folder path (the full path to the file at its original location)
- ParentID (beginning Bates number for the parent email or e-doc)
- Attchids (beginning Bates number(s) for the attachment(s) associated with a parent e-mail or e-doc)
- FamilyID (An ID that is unique to the entire family group (email and attachments))

- Family Date (for emails and attachments only, corresponding to the sent or received date of the email to which the attachment is linked)
- MessageID (emails only)
- Sent Date (for emails and calendar invitations)
- Sent Time (for emails and calendar invitations)
- Last Modified Date (all documents)
- Last Modified Time (all documents)
- Created Date (all documents)
- Created Time (all documents)
- Received Date (for emails only)
- Received Time (for emails only)
- Call Start (start date and time of a calendar or appointment)
- Last Accessed Date (all documents)
- Last Accessed Time (all documents)
- Last Print Date (for e-docs)
- Author (e-docs only)
- From (“From” field in emails)
- Recipients (“To” field in emails)
- cc: (for emails only)
- bcc: (for emails only)
- Subject (“Subject” field in emails)
- Participants (names included in a meeting invitation)
- Attach Title (email attachments title list)
- Application (type of application used to generate the document)
- Custodian
- Duplicate custodian (the name of any custodian whose duplicate file was removed during production)
- MD-5 Hash Value or SHA-1 Hash Value
- Page Count (number of pages in a document)
- Original File Name (the original file name of an e-doc or attachment to an email)
- Doc extension (the file extension of a document)

- Full Text (the full path to the OCR/extracted text file on Production Media)
- NativeLink (the full path to the native file produced)

Notwithstanding the foregoing, the Parties will meet and confer in good faith prior to the production of documents, with technical experts as needed, to clarify or resolve any issues (e.g., definitions of metadata fields, inconsistencies, burden) concerning the production of metadata.

K. Attachments. Email attachments and embedded files or links must be mapped to their parent by the Document or Production number. If attachments and embedded files are combined with their parent documents, then “BeginAttach” and “EndAttach” fields (or the functional equivalent, depending on the production format chosen) listing the unique beginning and end number for each attachment or embedded document must be included, when possible.

L. Load Files. The Parties agree to produce the following load files to accompany each production volume:

OCR and Extracted Text Files (.TXT Files):

- Single text file per document containing all the document's pages
- Pages separated by form feed character (decimal 12, hex 0xC)
- Filenames should be of the form:
`<Bates num>.txt`
Where <Bates num> is the BATES number of the first page in the document.
- Text must be encoded in UTF-8.

Image Files:

- Single page per image
- TIFF is Group IV compression, 300 dpi unless color or grayscale image is necessary, then .JPG would be acceptable
- Filenames should be of the form:
“<Bates num>.<ext>,” where <Bates num> is the BATES number of the page, and <ext> is the appropriate extension for the image format (.jpg, .tif).

Index Files:

- “Concordance Default” delimited text file utilizing the following characters:
 - The “comma” delimiter is “¶” (020)
 - The “quote” delimiter is “þ” (254)
 - The “new line” delimiter is “®” (174)
- First line must contain the column/field names (set forth in Paragraph 1(c) herein)
- Every row must have the same number of columns/fields (empty values are acceptable)
- All records must contain the quote “þ” character and the comma “¶” character for every entry.
- DATE Fields (cannot contain zeros such as, 00/00/0000 or 11/00/2012 value)
- Text must be encoded in UTF-8

M. Structured data. To the extent a response to discovery requires production of discoverable ESI contained in a database, in lieu of producing the database, the Parties agree to meet and confer, with an understanding of which fields are relevant, regarding queries to be made for discoverable information or upon the sets of data or fields to be included and generate a report in a reasonably usable and exportable electronic file (e.g., Excel or CSV format) for review by the Requesting Party or counsel. Upon review of the report(s), the Requesting Party may make reasonable requests for additional information to explain the database schema, codes, abbreviations, and different report formats or to request specific data from identified fields.

V. OBJECTIONS TO ESI PRODUCTION

A. Documents that present imaging or form production problems (including encrypted and/or protected files identified during the process of ESI) shall be promptly identified and disclosed to the Requesting Party; the Parties shall then meet and confer to attempt to resolve the problems.

VI. Miscellaneous

A. Cooperation. The Parties shall, as necessary, meet and confer to exchange information regarding issues associated with any electronic production of ESI and cooperate with one another to address matters relating to this Protocol.

B. Variance. Any practice or procedure set forth herein may be varied by agreement of the Parties without order of the Court. Failure of the Parties to agree on any modifications may be raised with the Court as necessary and in accordance with the Federal Rules of Civil Procedure and the Local Civil Rules.

So Ordered.



Hon. Rya W. Zobel
United States District Judge
Magistrate

Dated: April 10, 2014